Abstract

In spite of a long process of serious and complicated clinical trial during the research course of any drug, the occurrence of ADR is still inevitable. It appears to be normal to discover new dangers associated with a new drug after its delivery to the market, and this problem has become more serious than before. Hence, the WHO is very concerned about the relevant surveillance of ADR effects. In fact, the WHO requires every member country to develop and maintain a set of international standards for all the drugs that have been delivered to the market. It turns out to be true that the safety surveillance of the drugs on the market is more important. In order to enhance the surveillance of ADR, those supervising departments on drugs in many countries have stepped up the information collecting systems about ADR, as well as modifications of relevant drug supervising regulations. In short, enhancing ADR surveillance has become a main function of the Drug Supervising Department in many countries worldwide. In Hong Kong, a report system on ADR was established in October, 1986. As an international city, Macao has to speed up the process of setting up a well-established ADR report system for the purpose of keeping up pace with the advanced management skills on safety use of drugs.

With a thorough understanding of the difficulties and conflicts associated with the ADR report systems being used in the world, this thesis aims at developing applicable methods and strategies suitable for Macao's ADR survillance system. This is by means of taking references to relevant reports and research of the ADR systems adopted by the more advanced countries in this field including U. S. A., China and Europe. By the same token, relevant experiences of the adjacent countries and cities of Macao, including Taiwan, Singapore and Hong Kong, with regard to ADR concepts are considered and evaluated. How to select the most appropriate ADR devices which can fit the needs of this city turns out to be the core of the study, with a hope that the research result can point to the right direction of an effective ADR system of surveillance of Macao.

This thesis is divided as four parts as follows:

(1) To look into the report system, origins of reports, scope of reports, requirements of reports, report handlings and data feedbacks of the various ADR reporting systems among China, U. S. A., Europe and those countries or cities which are adjacent to Macao, with similar characteristics in order to understand the mechanism differences of each own, and alos comparisons are made. The results show that process of implementing the report system varies due to differences existing among medical systems and the development of

production and sales systems of pharmaceutical products in different countries.

(2) To look into the problems encountered with ADR reporting system in the world by analyzing relevant articles and making comparison studies. These include studies on limitation of surveillance on voluntary reporting system, a lack of an efficient and systematic method on ADR analysis, and inadequate knowledge of professionals.

(3) To understand the problems that the city will encounter while carrying out and ADR reporting system by visiting expert professionals in this regard, along with necessary site visits. At final, conclusions will be drawn by proposing solutions and appropriate strategies on a successful ADR reporting system.

(4)To make a conclusion based on all the data and experiences mentioned above, and to come up with an applicable ADR reporting system for the Macao area.

Key words: Pharmacovigilance, ADR, Spontaneous reporting